



# The effectiveness of gynaecology teaching associates in teaching pelvic examination to medical students

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## Accepted Manuscript

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**TITLE PAGE**

**The effectiveness of gynaecology teaching associates in teaching pelvic examination to medical students:**

**A randomised controlled trial**

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**ABSTRACT**

**Objectives** To assess whether teaching female pelvic examinations using gynaecological teaching associates (GTAs); women who are trained to give instruction and feedback on gynaecological examination technique, improves the competence, confidence and communication skills of medical students compared to conventional teaching.

**Study Design** Randomised controlled trial

**Setting** Ten University of Birmingham (UoB) affiliated teaching hospitals in the UK

**Population** 492 final year medical students

**Methods** GTA teaching of gynaecological examination compared with conventional pelvic manikin based teaching at the start of a five week clinical placement in obstetrics and gynaecology (O&G).

**Main outcome measures** Student's perception of their confidence was measured on a 10cm visual analogue scale (VAS). Domains of competence were measured by a senior clinical examiner using a standardised assessment tool which utilised 10cm VAS and by a GTA using a four point Likert scale. Assessors were blinded to the allocated teaching intervention.

**Results** 407/492 (83%) students completed both the intervention and outcome assessment. Self-reported confidence was higher in students taught by GTAs compared with those taught on manikins (median score GTA 6.3; vs. conventional 5.8;  $p = 0.03$ ). Competence was also higher in those taught by GTAs when assessed by an examiner (median global score GTA 7.1 vs. conventional 6.0;  $p < 0.001$ ) and by a GTA ( $p < 0.001$ ).

**Conclusions** GTA teaching of female pelvic examination at the start of undergraduate medical student O&G clinical placements improves their confidence and competence compared with conventional pelvic manikin based teaching. GTAs should be introduced into undergraduate medical curricula to teach pelvic examination.

**Keywords** Female pelvic examination, Gynaecology Teaching Associates, Confidence, Competence, Randomised controlled trial, Expert patient, Medical student, Undergraduate medical education

**Trial registration** Clinicaltrials.gov reference number NCT01944592

## INTRODUCTION

Physical examination of the pelvis is a core skill that medical students need to acquire. The intimate nature of the examination poses challenges to medical students and their teachers in gaining consent for supervised training [1,2]. However, other factors may now be affecting student experience. These include competing pressures on undergraduate medical curricula resulting in traditional clinical placements, such as obstetrics and gynaecology (O&G), becoming shortened in many academic institutions. Empowerment of patients combined with changes in their expectations may have further restricted students' access to clinical cases[3]. Clinical teachers may also have become less experienced such that they find teaching vaginal examination an increasing challenge.

Innovations are urgently required to enhance teaching of a skill, which is fundamental to both gynaecological and general medical practice. A strategy gaining popularity is simulation using 'expert patients' known as gynaecological teaching associates (GTAs)[4] [5–10]. These women have been trained to both undergo and teach gynaecological examination simultaneously providing instruction and immediate feedback to students. The use of GTAs is associated with significant improvements in student competence and modest improvements in communication skills and no apparent difference in student confidence[11]. However, data are scarce and heterogeneous, being limited to small observational and randomised series with typical samples less than 100 students [5,6,12]. However, most undergraduate medical programmes in the UK continue to teach pelvic examination using inanimate pelvic models (manikins) combined with

experience gained from supervised teaching on women attending outpatient clinics and those anaesthetised for surgery.

With opinion as to the value of GTAs not yet solidified and in the absence of rigorous scientific assessment of the educational benefits of GTAs, we undertook a large RCT to compare the effectiveness, in terms of student confidence and competence, of teaching female pelvic examination to medical students using GTAs when compared to conventional teaching.

## **METHOD**

The TARGET trial (Teaching Associates Randomised to evaluate the effectiveness of GTA taught pelvic Examination versus Traditional teaching using manikins) was a single blinded, parallel-group RCT to assess the effectiveness of GTAs teaching pelvic examination compared with conventional pelvic manikin based teaching (Clinicaltrials.gov NCT01944592).

Year five medical students beginning their O&G clinical placement at the University of Birmingham (UoB) were invited to participate in the study one week prior to commencement of their clinical placement. The TARGET trial was introduced to students by a member of the Birmingham Women's Hospital (BWH) undergraduate teaching faculty (AJ, TJC, JKG) during their introductory lecture on day one of their placement. Consenting students were recruited. All students were considered suitable for the trial, and there were no exclusion criteria. Third party randomisation was performed by the Birmingham Clinical Trials Unit (BCTU) at the end of day one of the clinical placement. Students were allocated in a 1:1 ratio through a telephone randomisation service. Randomisation blocks were stratified by student gender to ensure balance between groups. The randomisation blocks were kept centrally at the BCTU and varied in size so that allocation could not be deduced.

## Teaching interventions

Teaching of gynaecological pelvic examination took place within four days of randomisation after which the students went on to complete their standard five week clinical placements in O&G at 10 hospitals recognised as Clinical Teaching Academies for the UoB Medical School. All participating students were given a lecture on pelvic examination before being split into groups of four for a two hour teaching session. The content of the two hour session was dictated by whether the student was randomised to GTA teaching or conventional pelvic manikin based teaching. Those students who did not take part in the study received the standard teaching usually provided by their allocated hospital.

### *GTA teaching*

A pair of GTAs discussed the pre-examination gynaecological consultation including the process of consent and preparation of a patient with the students. This was followed by a role-play in a consultation room, where one played a patient and the other the medical student. Each student then conducted a gynaecological examination including abdominal palpation, speculum examination and bimanual examination with feedback on technique, pressure and communication skills from both the GTA being examined and the supervising GTA. The other students in the group all observed the active student. Once all students had completed conducting an examination they repeated the examination on the other GTA who was not examined initially, but this time they were allowed to perform the examination uninterrupted and feedback was provided at the end.

### *Conventional pelvic manikin based teaching*

The pre-examination gynaecological consultation, including the process of consent and preparation of a patient, was discussed with the students by a Clinical Lecturer from the undergraduate faculty. Any queries from students were addressed. Once this was completed, the Clinical Lecturer demonstrated a

gynaecological examination on a pelvic manikin. Each student then performed a pelvic examination, comprising speculum and bimanual examination on the manikin with feedback on technique and communication skills from the Clinical Lecturer. The other students in the group all observed the active student. Questions on examination technique were answered and students then repeated the examination on the pelvic manikin, but this time they were allowed to perform the examination uninterrupted and feedback was provided at the end.

## **Outcome measures**

### *Assessment of confidence and competence*

The level of student perceived confidence and competence was collected prior to teaching interventions to explore whether baseline confidence and competence differed between groups. Students rated their confidence and competence on an ungraduated 10 cm visual analogue scale (VAS). Student perceived confidence and competence at the end of their five week O&G clinical placement was evaluated in the same way on a 10cm VAS, immediately prior to an objective, summative assessment of competency. All self-reported student outcomes were collected using an anonymous questionnaire. (Appendix S1)

Objective student competence in performing gynaecological examination was assessed using an objective structured clinical examination (OSCE) station, which comprised a clinical scenario requiring the student to explain and conduct a speculum and bimanual examination of a female patient attending an outpatient clinic. The role of the patient was played by one of the GTA faculty and students were observed by a single passive examiner. Examiners were O&G Consultants or Specialist Trainees with an interest in medical education as well as familiarity in OSCE style assessments. The examiners assessed the students independently using a standardised assessment tool (Appendix S2) which comprised of seven domains relating to various communication and practical aspects of the procedure and a global assessment for competence. All domain responses were measured on an ungraduated 10cm VAS. In addition, the GTAs were asked to give an overall rating of the student's communication and clinical examination skills, as perceived by them in their patient role, on a four point Likert scale with response categories:



“Unsatisfactory”, “Borderline”, “Satisfactory” and “Good”. The examiners were blinded to the students’ teaching methods. The GTAs involved in the final assessment were allocated to students they had not taught in the GTA teaching session.

### *Secondary outcomes*

A number of secondary, self-reported student outcomes were collected by anonymous questionnaire, immediately prior to OSCE assessment of competency, to further assess the impact of initial teaching interventions on student experience during their five week clinical placements in O&G.

### **Sample size**

The sample size was estimated by identifying a useful improvement in student competence at undertaking female pelvic examination following GTA-based teaching over conventional teaching. In a previous, small randomised UK study[12], the average score in the final assessment of those students given extra training with GTAs was 77.1% compared to 59.2% for those on the standard training course. The standard deviations for all assessments ranged from 9.4 to 15.0. Moreover, from surveying Senior Academy Teachers at the BWH Clinical Teaching Academy, a 5% improvement in competence and confidence was considered clinically meaningful. Thus, by adopting a cautious approach and assuming a minimum significant improvement in results of 5% with a power of 90%, a significance of 0.05 (two tailed test) and a standard deviation of 15.0, we predicted we would need 200 students in each arm of the RCT. The sample size was inflated to 480 to allow for 20% loss to follow up (student drop out).

### **Statistical analysis**

Analysis was by intention to treat. Baseline characteristics of the students enrolled in the two groups were compared to ensure that randomisation had produced comparable groups of students. Categorical measures were presented as frequencies and percentages and analysed using chi squared statistics.

Analysis of normal plots and summary statistics guided which statistical analysis was performed for continuous variables measured on VAS. As almost all the data was not normally distributed, continuous variables were displayed as medians and interquartile ranges and analysis performed using the Mann-Whitney Test. All analysis was performed using SPSS software version 21.

## RESULTS

### Participants and follow up

492 medical students were recruited and randomised between August 2013 and December 2014, with 407 (83%) attending the final assessment. Baseline characteristics of the students in both groups were similar (Table 1). In total, 241/247 (98%) students randomised to the GTA group attended teaching compared with 240/245 (98%) in the conventional teaching group (Figure 1). Primary outcome responses were available from 407/481 (85%) participants who received teaching.

### Confidence in pelvic examination

At the end of the five week clinical placements in O&G there was a significant improvement in confidence from baseline in female pelvic examination for students in both the GTA group (median increase from baseline 3.8;  $p < 0.001$ ) and conventional teaching group (median increase from baseline 3.2;  $p < 0.001$ ). However, the degree of confidence in pelvic examination for those students taught by GTAs was higher (median score; GTA 6.3 [IQR 2.1] vs. conventional 5.8 [IQR 2.1];  $p = 0.03$ ).

### Competence in pelvic examination

There was no significant difference between the groups in self-reported competence at the end of the teaching block (median score; GTA 6.5 [IQR 2.0] vs. conventional 6.4 [IQR 2.0];  $p = 0.3$ ). However, objective third party assessment by examiners and GTAs consistently showed a better performance by students receiving GTA teaching in gynaecological examination across almost all measures. The global score for

competence assessed by examiners during the OSCE was significantly higher in those taught by GTAs (median score; GTA 7.1 [IQR 3.0] vs. conventional 6.0 [IQR 3.0];  $p < 0.001$ ). Those students taught by GTAs scored significantly higher than those taught conventionally in six elements of the pelvic examination but not for inspection (median score; GTA 7.1 [IQR 3.0] vs. conventional 6.7 [IQR 4.0];  $p = 0.5$ ) and the number that correctly identified the cervix (GTA 142/204 [70%] vs. conventional 126/201 [63%]; OR 1.41 [95% CI 0.93 to 2.13];  $p = 0.7$ ) (Table 2.). Assessment by the GTAs during the OSCE also showed a statistically significantly better performance by those taught by GTAs ( $p < 0.001$ ), (Table 3). A subgroup analysis was done for student sex as this was used as a stratification variable during randomisation. There were no significant differences between male and female students perceived confidence after training (median score; male 6.0 [IQR 2.4] vs. female 6.3 [IQR 2.0];  $p = 0.4$ ) and competence assessed by an examiner (median score; male 6.5 [IQR 3.0] vs. female 6.5 [IQR 3.0];  $p = 0.5$ ). Secondary outcomes are shown in Table 4.

## DISCUSSION

This RCT has shown that teaching of female pelvic examination to medical students by GTAs compared to conventional teaching by physicians is significantly better in terms of acquired competence and self-assessed confidence. Students trained by GTAs perceived their training method as being more useful and thought that GTA training had a greater impact on their subsequent exposure to gynaecological pelvic examination during their O&G placement. Those taught by GTAs performed significantly more examinations on conscious women in the clinical environment and reported being more satisfied with these opportunities. Students taught by GTAs were also found to be more competent than those receiving conventional teaching when evaluated by trained examiners and the GTAs themselves. Enhanced competence was not just restricted to global assessment but also observed in all individual elements of the pelvic examination (attitude, speculum examination, bimanual examination of the uterus, examination of the adnexa and pouch of Douglas and post examination feedback) with the exception of the domain of inspection and identification of the cervix where no differences were observed between groups.

The strengths of this trial include the strict randomisation process minimising although not eradicating confounding factors such as prior student performance, experience and location of hospital placement. The sample size was large and examiners were blinded to the teaching method of the students. Only a small proportion, 59/551 (10%), declined to participate enhancing the generalisability of our results. The 20% loss to follow up was acceptable; to optimise follow up students had been informed that the evaluation would not contribute towards their final degree marks and that they would receive immediate feedback regarding their performance. However, it appears that the combination of the pressure of an assessed clinical examination and time taken out of study and recreation during the final year dissuaded a minority of students to attend. Some limitations of our trial should be noted. In the absence of a validated competency assessment tool in female pelvic examination we used a bespoke OSCE developed and used for over three years by our undergraduate faculty and which appears to have face validity. Undergraduate medical student and examiners are familiar with OSCEs and so we believe that our competency assessments are valid and reproducible. Finally, students were examined five weeks after their initial training and immediately after completion of their O&G teaching block such that the sustainability of the imparted knowledge and skills in the longer term is unclear.

Published studies evaluating the effectiveness of GTAs are limited to small observational and randomised series with typical samples less than 100 students[11]. Overall, these data suggest that GTA teaching of pelvic examination is associated with significant improvements in student competence, modest improvements in communication skills and no apparent difference in student confidence compared with other teaching methods[11]. There have been a few previous RCTs that have indicated teaching of pelvic examination by GTAs is effective[5,6,12]. However, these were small trials that provided the GTA teaching as additional training, so it is hard to distinguish whether the benefit was conferred through the extra time spent teaching rather than the efficacy of the teaching method.

Evidence from this trial confirms that the GTA programme in its current design was effective in achieving better key educational outcomes compared to conventional teaching i.e. an increase in confidence and competence. Educators can confidently use GTAs to replace or supplement existing methods to teach competence in female pelvic examination and so help improve the current suboptimal situation. Experience of intimate examination is not restricted to gynaecological assessment[13] and so medical schools should consider employing GTA equivalents to assist with other intimate assessments such as uro-genital, breast, rectal, and prostate examinations if the findings of our trial can be replicated in other disciplines.

Research into the timing, frequency and duration of GTA sessions is needed. The development of validated assessment tools to assess competence will aid such research studies. Exploring whether postgraduate trainees early in their O&G career would benefit from GTAs for simple and complex pelvic examination teaching could be investigated in addition to undergraduate training. Future studies should also aim to identify which students may respond better to GTA teaching whilst also exploring attitudes and anxieties related to intimate examination through qualitative research.

#### **Disclosure of Interests**

Competing interests: All authors declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

#### **Contribution to authorship**

All authors meet the ICJME criteria for authorship. In detail: NR, SM and TJC recruited and trained the GTAs. TJC, PS and AJ designed the study with input from JP, JKG and SI. AJ conducted the study; collected and analysed the data with TJC and PS. PS provided statistical support. AJ, PS and TJC wrote all drafts of the manuscript. TJC supervised the study. All authors (JC, IG, RS) revised the manuscripts for important intellectual content.

**Details of ethics approval**

Ethical approval was provided by the University of Birmingham Ethical Review Board. Approval number ERN\_130476. All participants gave informed consent before taking part.

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**Condensation**

A large randomised controlled trial demonstrating that gynaecology teaching associates use in obstetrics and gynaecology enhance student confidence and competence in female pelvic examination skills.

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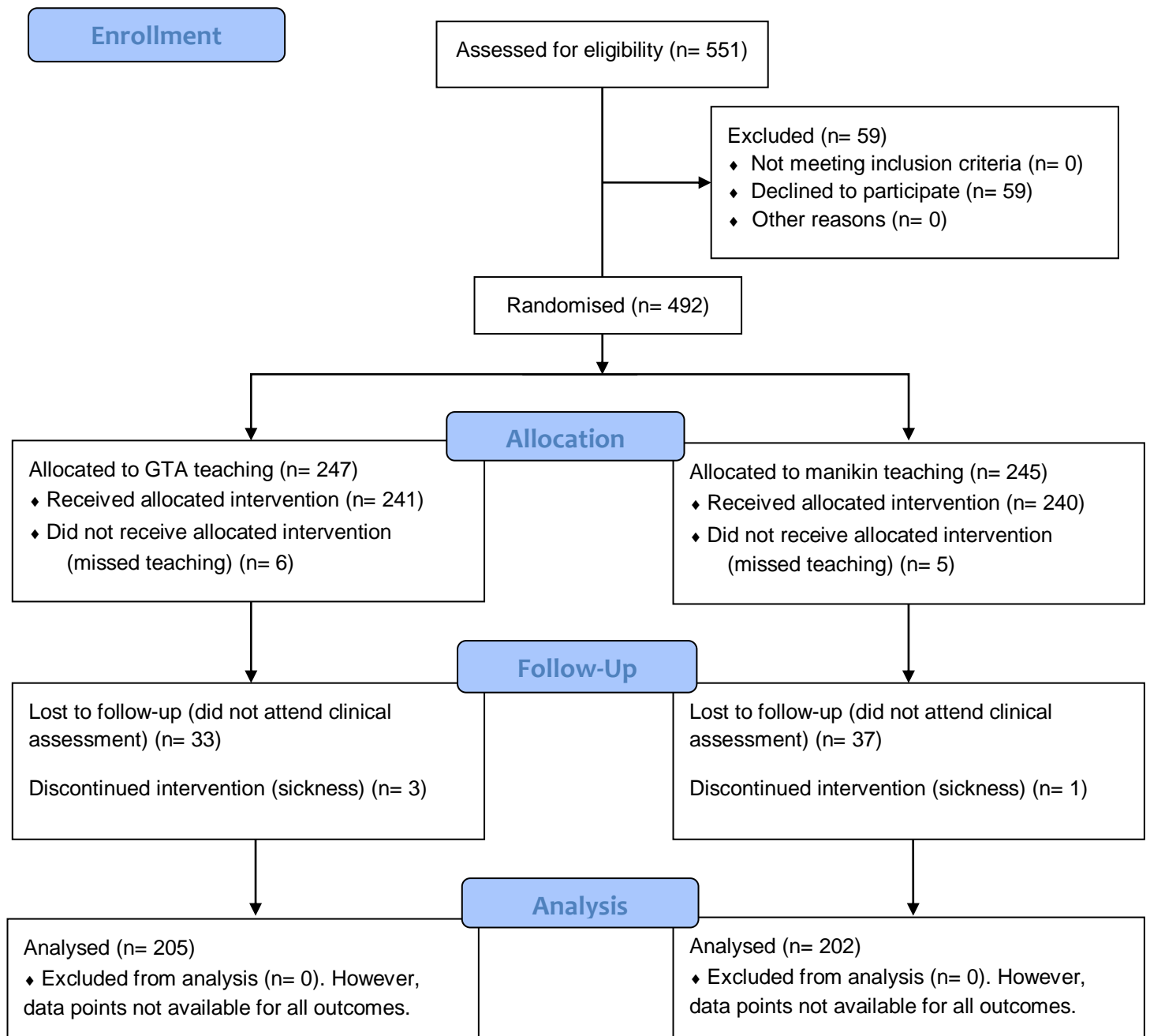
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**Figure 1**

CONSORT Diagram for TARGET Trial





**Table 1**

Baseline characteristics of students. Values are numbers (percentages) unless stated otherwise

Characteristics		Gynaecological teaching associates (n=247) n (%)	Conventional faculty teaching with manikins (n=245) n (%)
<b>Demographics</b>			
<b>Gender</b>	Female	161 (65)	158 (65)
	Male	86 (35)	87 (35)
<b>Age</b>	20-23	159 (64)	171 (70)
	24-26	67 (27)	58 (24)
	27-30	17 (7)	9 (4)
	>30	4 (2)	6 (2)
<b>Ethnicity</b>	White	166 (67)	160 (65)
	Asian	54 (22)	59 (24)
	Black	3 (1)	5 (2)
	Mixed	7 (3)	8 (3)
	Other	13 (5)	10 (4)
<b>Pre-Trial Gynaecological Experience</b>			
<b>Number of previously performed pelvic examinations on a female patient</b>	0	73 (30)	57 (23)
	1 to 5	163 (66)	183 (76)
	6 to 10	7 (3)	3 (1)
	>10	2 (1)	0 (0)
<b>Interest in a future career in obstetrics and gynaecology</b>		3.7 (3.0) <sup>1</sup>	3.4 (3.0) <sup>1</sup>

1 Median (interquartile range)

**Table 2**

Examiner results at objective structured clinical assessment of student competencies in female pelvic examination

	<b>Gynaecological teaching associates</b>	<b>Conventional faculty teaching with manikins</b>	
	<b>Median[IQR] or N (%)<sup>2</sup></b>	<b>median[IQR] or N (%)<sup>2</sup></b>	<b>p<sup>1</sup></b>
<b>Attitudes</b>	8.2[3.0]	7.2[3.0]	0.001
<b>Inspection</b>	7.1[3.0]	6.7[4.0]	0.5
<b>Bimanual Examination</b>	6.7[3.0]	5.8[3.0]	0.001
<b>Adnexa and Pouch of Douglas</b>	6.3[4.0]	5.7[3.0]	0.006
<b>Speculum Examination</b>	6.8[3.6]	5.8[3.4]	0.001
<b>Post Examination</b>	7.0[3.0]	6.3[4.0]	0.003
<b>Global Assessment</b>	7.1[3.0]	6.0[3.0]	<0.001
<b>Mean Score</b>	7.0[3.0]	6.3[2.8]	0.001
<b>Cervix Viewed</b>	142/204 (69.6%)	126/201 (62.7%)	0.7

IQR = interquartile range; 1 = Mann U Whitney test or Chi-square analysis, where appropriate; 2 = numbers vary between 199 & 204 for the GTA group, and between 199 & 201 for the manikin group, according to responses received as some 100mm VAS left blank by assessors

**Table 3**

Gynaecological teaching associate assessment of student competencies in female pelvic examination

<b>Gynaecological Teaching Associate Assessment</b>	<b>Gynaecological teaching associates (N=203) n (%)</b>	<b>Conventional faculty teaching with manikins (N=199) n (%)</b>	<b><i>p</i><sup>1</sup></b>
<b>Good</b>	113 (56)	60 (30)	<0.001
<b>Satisfactory</b>	65 (32)	95 (48)	
<b>Borderline</b>	15 (7)	27 (14)	
<b>Unsatisfactory</b>	10 (5)	17 (9)	

<sup>1</sup> = P value for trend using regression analysis.

**Table 4**

Post-teaching questionnaire results exploring student opinions and experience during clinical obstetrics and gynaecology placements

Characteristics		Gynaecological teaching associates median; IQR (number) <sup>3</sup>	Conventional faculty teaching with manikins median; IQR (number) <sup>3</sup>	P <sup>1</sup>
Perceived <u>usefulness</u> of training method received at the start of O&G block		8.7; 2.1 (203)	8.1; 2.1 (201)	<0.001
<u>Number of pelvic examinations</u> performed during O&G placement	0	6 (3%)	9 (5%)	0.4 <sup>2</sup>
	1 to 5	114 (56%)	116 (59%)	
	6 to 10	70 (34%)	60 (30%)	
	>10	14 (7%)	13 (7%)	
Number of pelvic examinations performed with patient awake		3.0; 4.0 (194)	2.0; 4.0 (192)	0.02
Number of pelvic examinations performed with patient under general anaesthetic		1.0; 3.0 (200)	2.0; 3.0 (194)	0.2
<u>Perceived Impact</u> of initial training i.e. manikin / GTA on experience and exposure to gynaecological pelvic examination during the O&G placement		7.1; 2.0 (200)	6.4; 3.0 (199)	<0.001
<u>Overall satisfaction</u> with the opportunity to <u>undertake pelvic examination</u> during O&G placement		6.6; 2.3 (204)	6.0; 3.2 (201)	0.02
<u>Overall satisfaction</u> with the O&G <u>placement</u>		7.6; 2.0 (201)	7.8; 2.0 (200)	0.7
Interest in <u>future career</u> in O&G		4.7; 4.0 (201)	5.0; 4.0 (200)	0.9

IQR = interquartile range; 1 = Mann U Whitney test unless otherwise specified; 2 = P value for trend using regression analysis; 3 = numbers vary according to responses received as some 100mm VAS left blank by students.